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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	CR-18-00258-EJD
)	
Plaintiff,)	JOINT STATUS MEMORANDUM
)	
v.)	
)	
ELIZABETH HOLMES and)	
RAMESH “SUNNY” BALWANI,)	
)	
Defendants.)	
)	

The parties in the above-captioned matter hereby file this joint status memorandum in advance of the hearing set for October 2, 2019. Statements from the government (Section I) and from the defense (Section II) are set forth below.

I. Government’s Statement

A. Background Regarding Defendant’s Motion and Agency Documents

After Defendants filed their Motion to Compel production of documents from FDA and CMS (Dkt. No. 67), the parties briefed the matter, and the Court received information from FDA and CMS themselves. As explained in the government’s briefing, Defendants’ Motion turns on the proper scope

1 of the government's discovery obligations. Defendants do not contest that those obligations apply only
2 where the prosecution has access to the materials in question. Here, the prosecution has shown that it
3 lacks access to the documents identified in Defendants' Motion—documents which are in the
4 possession, custody, and control of FDA and CMS themselves. That fact means that those materials are
5 not covered by the government's obligations under Rule 16 and *Brady*. Nonetheless, the government
6 has never objected to Defendants obtaining these materials. Thus, on May 9, 2019, the government sent
7 written requests to FDA and CMS asking for all of the document categories listed in Defendants' filing.
8 In response, the agencies noted the challenges associated with providing those documents, but agreed to
9 produce them.

10 Specifically, on July 9, 2019, FDA sent a letter to counsel for the government and for Defendants
11 confirming that it was "working diligently to collect, process, review, and ultimately produce all
12 documents responsive to all six categories requested by the parties." (Dkt. No. 89-2). On July 12, 2019,
13 CMS sent a similar letter to the parties restating its agreement to produce documents in its possession
14 responsive to the categories included in the government's written request. (Dkt. No. 89-3).

15 After reviewing the agencies' submissions, the Court issued an order on July 19, 2019 directing
16 FDA and CMS to produce responsive materials. (Dkt. No. 111). The Court's Order acknowledged the
17 agencies' cooperation and noted their agreements to produce. Although the Court did not accept the
18 agencies' proposed timelines for production, it took the agencies at their word that they would diligently
19 search for and produce the responsive documents. *Id.* Regarding timing, the Court ordered the agencies
20 to complete their productions no later than October 2, 2019 and to advise the parties by September 23,
21 2019 whether they anticipated completing their productions by the deadline.

22 **B. Production Progress Since the Court's Order**

23 The government forwarded the Court's July 19 order to the agencies and discussed the
24 requirements with agency counsel. The agencies reiterated their intentions to produce responsive
25 documents and indicated that they would produce on a rolling basis, allowing the parties to monitor the
26 progress of their productions. Contemporaneously, the government secured a waiver from the Theranos
27 assignee allowing disclosure of Theranos information. The government had previously drafted and
28 negotiated a stipulated protective order addressing the agencies' other stated concerns.

1 After completing significant portions of their productions, the agencies concluded that their
2 reviews could be further expedited if the Court entered an additional protective order providing that the
3 production of FDA and CMS documents would not constitute waivers of the agencies' privileges or
4 protections. The government subsequently negotiated such a protective order with Defendants, and the
5 Court entered the order on September 17, 2019. (Dkt. No. 120). The agencies' productions then
6 proceeded as contemplated, with FDA and CMS making a combined six productions to the parties. The
7 agencies made their productions to Defendants directly to avoid unnecessary delay.

8 On September 23, 2019, FDA and CMS sent letters to government counsel providing updates
9 regarding their respective productions. The letter from CMS is attached hereto as **Exhibit A**. FDA's
10 letter is attached as **Exhibit B**. As stated in its letter, CMS is on track to produce all responsive, non-
11 privileged documents by the October 2 deadline or shortly thereafter. CMS's total document production
12 will consist of nearly 14,000 documents, and the final portion of that production is currently being
13 processed by DOJ's Litigation Technology Service Center on the East Coast.

14 As to FDA, the agency expects to be in substantial compliance with the Court's order as of
15 October 2. To date, FDA has collected more than 150,000 documents and made four productions to the
16 parties totaling more than 25,000 pages. That progress was achieved thanks to a special arrangement
17 with FDA's parent agency allowing for use of an electronic document review platform. As explained in
18 the letter, approximately half of the documents collected by FDA in response to these requests were
19 determined through metadata to be duplicative of FDA's previous productions, which all parties have
20 received. Of the remaining documents, FDA subsequently used textual analysis to identify another
21 40,000 documents as potential duplicative, and are currently working to confirm that those documents
22 are indeed duplicates. That review is mostly complete. The government understands that, by
23 approximately October 2, 2019, FDA will have completed its review and production of documents not
24 flagged as duplicates, such that Defendants will have received the vast majority if not all of the
25 information responsive to their requests. The FDA's remaining tasks are to complete its review of likely
26 duplicative documents and continue attempts to resolve some technical issues it has encountered. It
27 reports that it will need less than one month to complete those tasks, and that this additional work is
28 unlikely to lead to the production of novel information.

1 **C. Defendants' Complaints**

2 On September 25, 2019, the parties met and conferred regarding the current status of the
3 agencies' document productions. During that conversation, defense counsel expressed dissatisfaction
4 with certain aspects of the agencies' productions. Defendants' complaints would best be resolved
5 through a meet-and-confer discussion with the agencies themselves. In the meantime, the prosecution
6 offers the following responses based on the information available to it.

7 **1. CMS's Use of Date Restrictions**

8 Defendants object to CMS's use of date restrictions to focus the agency's search for responsive
9 documents. The Court should disregard this objection for several reasons. *First*, the agency has made a
10 good faith determination that this date range appropriately captures the documents responsive to
11 Defendants' requests. The agency arrived at that date range based on its discussions with defense
12 counsel and its knowledge regarding its interactions with Theranos. The agency believes that its
13 responsive documents from the time period before September 1, 2013 have already been captured and
14 produced in its previous productions. Defendants have presented insufficient reason to doubt the
15 agency's judgment regarding how best to locate and produce responsive documents.

16 *Second*, the government understands that Balwani's counsel were agreeable to this date range
17 when meeting and conferring with CMS regarding the agency's response to Balwani's subpoena in the
18 SEC civil case—a subpoena seeking a broad range of documents of which the six categories here are a
19 subset. That meet-and-confer process stalled when the parties could not reach agreement on other terms,
20 but Balwani's apparent satisfaction with that date range in the civil case undercuts any complaint by
21 Defendants now.

22 *Third*, and finally, CMS has always been transparent with the parties and the Court that it
23 intended to rely on this date limitation in responding to the government's document requests. The
24 agency's July 12, 2019 letter prominently featured that date range, expressly stating that CMS intended
25 to limit its search for documents between September 1, 2013 and December 31, 2016. In fact, the Court
26 quoted that portion of CMS's letter in noting the agency's agreement to diligently search for and
27 produce responsive documents. In previous proceedings, Defendants offered no compelling reason for
28 CMS to deviate from this date range. To the extent Defendants did object, the Court's July 19, 2019

1 Order citing CMS's date range can be read as implicitly overruling those objections.

2 Regarding FDA, defense counsel complained that the agency's letter does not specify whether it
3 also relied on a date restriction in collecting and producing documents. The prosecution has
4 subsequently confirmed with agency counsel that FDA, like CMS, faithfully applied the date range that
5 it disclosed in its earlier letter to the parties, that is, January 1, 2010 through June 30, 2018.

6 **2. FDA Redactions**

7 Without citing specific examples, Defendants also have objected to certain redactions contained
8 in FDA's production. Defendants have not shown, however, that FDA withheld any responsive,
9 discoverable information. In FDA's July 9, 2019 letter, the agency explained that it could not produce
10 certain categories of information including third-party trade secret and confidential commercial
11 information. That letter also stated that FDA intended to withhold or redact attorney-client
12 communications, attorney work product, and personal / private information. That FDA followed
13 through on these plans should not come as a surprise to Defendants.

14 Since learning of Defendant's complaint, government counsel has consulted with FDA counsel
15 regarding the bases for the redactions in the agency's production. Agency counsel, in turn, has informed
16 the government that it redacted information in the following categories: (1) attorney-client / work
17 product; (2) non-Theranos-related deliberative process privileged information; (3) personal privacy
18 information; (4) third-party (non-Theranos) trade secret and confidential commercial information; and
19 (5) non-responsive information wholly unrelated to Theranos. These categories appear to be appropriate
20 bases for redaction, they are consistent with FDA's previous statements regarding its plan for
21 production, and they do not violate the Court's July 19 Order. Defendants have not advanced any
22 substantive arguments to the contrary. Indeed, Defendants are in no position to argue—much less
23 prove—that FDA improperly redacted without first discussing those redactions with the agency and
24 gathering additional information regarding the nature of the withheld information. A meet and confer
25 between defense counsel and agency counsel seems a reasonable next step to address any such concerns.
26 The Court should decline to require any further action on FDA's part at this time.

27 **3. Disclosure of Custodians and Search Terms**

28 Finally, Defendants complain that they are unable to judge the agencies' compliance with the

1 government's requests and the Court's order because they do not have information regarding the
2 identities of the custodians from whom the agencies collected or a list of any search terms the agencies
3 used to identify responsive documents for review. But Defendants provide no authority for the
4 proposition that they are entitled to know the specifics of the agencies' collection efforts, or to dictate
5 the exact steps the agencies take to respond to the government's document requests and the Court's
6 order. FDA's July 9 letter provided the parties with information regarding the large number of
7 custodians from whom it was collecting. That letter also referenced the agency's plans for avoiding
8 duplication of prior work and for prioritizing review of materials from the custodians most likely to have
9 documents responsive to Defendants' requests. Substantively, Defendants have made no showing that
10 the agencies did not use their best efforts to execute those plans and comply with the document requests
11 at issue. And even if the agency documents were covered by Rule 16 or *Brady*—and they are not—
12 those rules do not support Defendants' current demands for even more details regarding the agencies'
13 collection methods. Under these circumstances, Defendants should accept the agencies at their word as
14 the Court did in its July 19 Order.

15 Moreover, it bears noting that Defendant's Motion relies heavily on the argument that FDA and
16 CMS previously produced documents in response to the prosecution's requests during the criminal
17 investigation. According to Defendants, the fact that the government was previously able to obtain these
18 materials establishes the government's full access to all agency documents. (*See* Mot., Dkt. No. 67, at
19 12-13). But when the prosecution made those original document requests, it left it to the agencies to
20 make their own determinations about the mechanics of collecting and producing responsive documents.
21 Through discussions with the prosecution and the agencies themselves, Defendants have been
22 significantly more involved in the specifics of the agencies' recent production. Thus, if Defendants'
23 rights to obtain agency documents depend on the prosecution's degree of access, those rights have been
24 fully satisfied.

25 To the extent this issue requires any further action from the agencies, the first step should be a
26 meet-and-confer discussion between defense counsel and the agencies rather than an order from the
27 Court.

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II. Defendants' Statement

The Court's July 19, 2019 Order was clear. It required the FDA and CMS to advise the Court by September 23, 2019 "whether they anticipate completing their productions by the" October 2, 2019 deadline. Order at 5, ECF No. 111. The Order also required the FDA and CMS to keep the prosecution "reasonably apprised of the status of their productions" before that interim report, and that the prosecution "shall share such information with Defendants." *Id.*¹ The agencies have made a series of rolling productions with a small number of documents. Until their September 23 letters, however, the agencies and the prosecution have kept the defense almost entirely in the dark on the status of their overall production efforts or the steps the agencies had taken to ensure timely and complete compliance with the Court's order, information which was required to be shared with the Defendants by the Court's Order. And the agencies' September 23 letters raise more questions than they answer.

As an initial matter, neither agency pledges in its September 23 letter that it will be in compliance with the Court's order by the October 2, 2019 deadline. Rather, the FDA letter speaks of "substantial compliance" and CMS similarly does not commit to completing its productions by the deadline. In fact, the agencies' representations regarding the status of their productions continue to be cryptic and artfully worded, and only underscore the continued and pressing need for a Rule 16 order to ensure that all responsive documents are produced to the Defendants by making the DOJ directly accountable. Indeed, even the small production of 2,249 documents by the FDA, the total from the FDA during the two months since the last hearing, contains highly significant *Brady* material that directly contradicts Paragraph 12 of the Superseding Indictment. The DOJ has the experience, obligation, and should have the responsibility to ensure that all agency documents are carefully reviewed for *Brady* as the Court has made clear that the government's "constitutional responsibility under Rule 16 ... remains."² The government is *not* "off free from anything."³

¹ The defense's motion established that the government has knowledge of and access to the materials and therefore obligations under Rule 16 and *Brady* to produce this material. *See* Dkt. 67; *United States v. Bryan*, 868 F.2d 1032, 1036 (9th Cir. 1989); *United States v. Santiago*, 46 F.3d 885, 893-94 (9th Cir. 1995).

² Transcript of Proceedings Before the Honorable Edward J. Davila (July 16, 2019), at 40:6-17.

³ *Id.* at 40:15-16.

1 In addition, both agencies report that the bulk of the documents they intend to produce under the
2 Order have not yet been produced to the defense. That is especially true of CMS, where the estimated
3 number of outstanding documents dwarfs the number that it has produced by a factor of more than four.
4 Moreover, the number of documents and pages produced quoted in their letters overstates the breadth of
5 those productions. In the case of the FDA, large swaths of documents have been redacted as not
6 responsive, often excising the context necessary to understand the communication, and many other
7 documents appear to be Google alerts and similar non-substantive emails. The FDA has also failed to
8 produce a log of the “public” documents the FDA is withholding, despite the fact that this very issue
9 was discussed with the Court at the last hearing.⁴ Further, a preliminary review of what has been
10 produced suggests substantial gaps, including documents missing from key FDA custodians. To give
11 one example, the FDA has not produced any communications before December 2013, and the vast
12 majority of the communications produced by the FDA thus far were created in the mid-to-late 2015 time
13 period. *See Exhibit C* (Histogram of 1,754 Emails Produced to Defendants by FDA). This is very
14 surprising in view of the very frequent interaction between the FDA and Theranos throughout at least
15 the period 2012 through 2016. The FDA’s productions so far also do not appear to include any internal
16 FDA documents discussing the lead-up to the FDA’s August 2015 inspection, as the Defendants would
17 have expected.

18 An even larger issue, however, is that the defense is not in a position to assess whether the
19 agencies have complied with the Court’s Order when the majority of the documents have not yet been
20 produced. And that is not anticipated to occur until *after* the deadline set by the Court. Likewise, the
21 defense also lacks any information about how the agencies conducted their searches. What search terms
22 did they employ? From which custodians were documents collected? How did they go about collecting
23 documents from these custodians? The agencies’ September 23 letters, though they contain many
24 words, do not communicate any of this useful information. Critically, for all their verbiage, the letters
25 do not answer a simple question that Defendants have been asking for months: do the agencies intend to
26 produce *all* documents responsive to the Motion and the Court’s orders? The September 23 letters
27

28 ⁴ See Transcript of Proceedings Before the Honorable Edward J. Davila (July 16, 2019) at 22:21-23:18.

1 suggest that their answer would be no. And by when? These unanswered questions only underscore the
2 need for the DOJ to ensure that all responsive documents are produced and certify to the Court that the
3 DOJ's Rule 16 and *Brady* obligations have been met.

4 CMS, for example, has unilaterally selected a time period starting on September 1, 2013 on the
5 basis that CMS believes a range with this starting point will "reasonably capture[]" documents
6 responsive to the Motion and Order. But the requests in the Motion and Order do not contain a date
7 cutoff, and Ms. Holmes made clear in her pleadings that CMS likely has responsive documents dating
8 back to at least 2012 given that Theranos's CLIA certification began in June 2011. Any production
9 based on this timeline would not include all responsive documents under the Court's Order. CMS's
10 unilateral narrowing of the scope of the request also stands in direct contravention of the Court's
11 comments in the June 28, 2019 hearing when the Court stated that the agencies do not get to make
12 determinations of relevance and usefulness in responding to the requests in the Motion. This unilateral
13 action raises questions of responsibility and accountability for this discovery previously identified in the
14 Motion and at oral argument.

15 The government suggests that the Defendants have somehow agreed to CMS's narrowing of the
16 relevant time period. Absolutely not. Ms. Holmes did not participate in negotiations that took place in
17 the SEC action to which she is not a party, and has previously demonstrated that responsive documents
18 likely would be found at least back to 2012. Any negotiations that occurred regarding the appropriate
19 date range to apply to CMS's searches for documents occurred in Mr. Balwani's case against the SEC
20 and were never finalized. The DOJ's attempt to cherry pick communications in the SEC case in order to
21 skirt its Rule 16 and *Brady* obligations is inappropriate.⁵

22 In sum, the defense cannot assess the agencies' efforts at compliance with the Order based on
23 their concededly incomplete productions and cryptic correspondence, but the information the agencies
24 have provided raise serious concerns that these productions are far from complete. The Court can cut
25 through the fog that these letters engender. The Court should hold the DOJ directly accountable to

26
27 ⁵ The Court's order did not "implicitly overrule[]" any objection to a limited date range. The
28 order noted that the productions should include "all documents responsive to the six categories of
documents described above, *i.e.*, the six categories stated in Defendants' Motion." Order at 5.

1 answer the simple question at the core of this dispute: can the prosecution team represent that they are
 2 (or soon will be) in full compliance with the Court's order by producing *all* responsive documents in
 3 their possession? Because the DOJ has not yet assumed accountability, the Court should also require the
 4 agencies' attorneys to attend the October 2, 2019 hearing to explain when they will be in full compliance
 5 with the Court's Order.

6 Time for compliance grows short. A trial date lurks. We are weeks beyond an agreed upon
 7 deadline for full Rule 16 production. These agencies are nowhere near providing the documents the
 8 defense needs. While DOJ's pleas of distance from the process are designed to spare it from ensuring
 9 compliance, that will not save the trial from prejudicial error. The Court should order the DOJ to
 10 assume accountability for the full production so that it can certify when the government agencies have
 11 fully complied with the Order.

12
 13 DATED: September 30, 2019

Respectfully submitted,

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